

REMARKS

The Office action rejects:

- I. claims 1, 2, 5, 10, 20, 27 and 28 under 35 U.S.C. §102(b) over *Gotsche et al* (WO/00/18375);
- II. claim 7 under 35 U.S.C. §103(a) over *Gotsche et al* in view of *Castillo et al.* (US 5,091,185);
- III. claim 11 under 35 U.S.C. §103(a) over *Gotsche et al* in view of *Babaian et al.* (US 4,842,854); and
- IV. claims 29 and 30 under 35 U.S.C. §103(a) over *Gotsche et al.*

Regarding Rejection I:

The Examiner should withdraw the rejection of claims 1, 2, 5, 10, 20, 27 and 28 under 35 U.S.C. §102(b) over *Gotsche et al* (WO/00/18375).

Claim 1 is directed to a quick dissolving film coating composition for coating solid substrates, composed of:

component A: 10 – 90% by weight of a polyvinyl alcohol-polyether graft copolymer,

component B: 5 – 80% by weight of at least one further component containing at least one functional group selected from the group consisting of hydroxyl, amide and ester functions, and

optionally **component C.**

In order for this composition to be anticipated, “[t]he identical invention must be shown in as complete detail as is contained in the patent claim.”¹ Yet, the Office action states that “Component A is clearly anticipated by *Gotsche et al.* [and, therefore,] the issue of species selection is irrelevant”²

The present invention is not merely component A. The present invention is a composition. The inventive composition must comprise component A and component B. The inventive composition must comprise 10 – 90% by weight of component A, and 5 –

¹ *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

² Page 5, line 21 of the final Office action mailed December 10, 2007

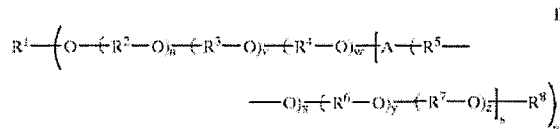
80% by weight of component B. In order for the inventive composition to be anticipated a single prior art reference must show the identical composition. It is not enough that a single prior art reference discloses both components A and B in isolation.

Contrary to the statement in the Office action that the issue of species selection is irrelevant because component A is disclosed in an enormous genus, applicable law mandates that the issue of species selection is of paramount importance. Moreover, common sense and justice both demand that the issue of species selection be given due consideration. Otherwise, a sales catalogue of all known chemical compounds would anticipate any future combination of chemicals.

According to the Office action, Component A of present claim 1 is included in the enormous genus encompassed by column 3, indicated lines 5 – 41 of *Gotsche et al.* (US 6,579,953), which discloses:

polymers, in particular polymers which are soluble or dispersible in water and are obtainable by polymerization of

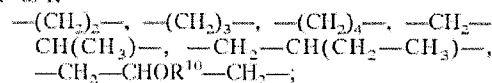
- a) at least one vinyl ester of aliphatic C₁-C₂₄-carboxylic acids, in the presence of
- b) polyethers of the general formula I,



in which the variables have, independently of one another, the following meanings:

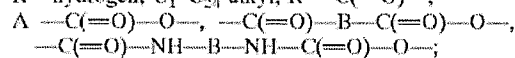
- R¹ hydrogen, C₁-C₂₄-alkyl, R⁹-C(=O)-, R⁹-NH-C(=O)-, polyalcohol residue;
 R⁸ hydrogen, C₁-C₂₄-alkyl, R⁹-C(=O)-, R⁹-NH-C(=O)-;

R² to R⁷



R⁹ C₁-C₂₄-alkyl;

R¹⁰ hydrogen, C₁-C₂₄-alkyl, R⁹-C(=O)-;



B -(CH₂)_r-, arylene, optionally substituted;

n 1 to 8;

s 0 to 500;

t 1 to 12;

u 1 to 5000;

v 0 to 5000;

w 0 to 5000;

x 1 to 5000;

y 0 to 5000;

z 0 to 5000

The Examiner has argued that Component B of present claim 1 is included in the genus encompassed by column 12, indicated lines 9 – 21, which discloses:

It is also possible to combine the polymers used according to the invention with other film formers or polymers in the ratio from 1:9 to 9:1.

Examples of polymers which can be employed for this purpose are the following:

polyvinylpyrrolidone, polyvinylpyrrolidone copolymers, water-soluble cellulose derivatives such as hydroxypropylcellulose, hydroxypropylmethylcellulose, methylcellulose, hydroxyethylcellulose, acrylate and methacrylate copolymers, polyvinyl alcohols, polyethylene glycols, polyethylene oxide/polypropylene oxide block copolymers.

The Office action misapplies the law by stating that “when the species is clearly named, the species is anticipated no matter how many other species are additionally named.”³ In response, applicants respectfully reemphasize that “[w]hen [a claimed] compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine [those portions], ... anticipation can only be found if the classes of substituents are sufficiently limited or well delineated.”⁴

To arrive at the present invention, a skilled artisan needed to do more than make a single species selection. In fact, a skilled artisan needed to do more than make two species selections. In order to arrive at the claimed invention a skilled artisan would have needed to:

- select component A from an enormous genus which is not sufficiently limited or well delineated to support anticipation,
- select component B from a second broad genus which is not sufficiently limited or well delineated to support anticipation, and
- for some unknown reason combine components A and B.

When the present invention is appropriately considered as a whole, it is clear the *Gotsche et al.* reference does not disclose “[t]he identical invention ... in as complete detail as is contained in the patent claim.”⁵ Thus, applicants respectfully submit that the reference does not anticipate the present invention.

Since the examiner has not rejected these claims under 35 U.S.C. §103, and since a case of *prima facie* obviousness cannot be established because of the shortcomings of the *Gotsche et al.* reference, a showing of unexpected results is in no way required. However, in order to emphasize the importance of the claimed invention, Applicants would like to make note that the present specification discloses synergistic effects which could not have been foreseen by the skilled artisan on the basis of the *Gotsche et al.* reference. As is explained on page 7, line 23 to page 9, line 35 of the specification, the combination leads to enhanced mechanical properties like elongation at break which are

³ Page 6, lines 6 – 8 of the final Office action mailed December 10, 2007

⁴ MPEP §2131.02, citing *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (emphasis added).

⁵ *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

higher than the properties of the individual compounds or their respective proportionate values. Since the coatings contain 40% by weight of polyvinyl alcohol, a polymer which tends to become brittle and is not at all stable when stored on its own, the results shown on the 2nd table of page 8, reporting elongation at break after various storage times are especially surprising. The coatings remain stable even after 12 months.

Regarding Rejection II:

The Examiner should withdraw the rejection of claim 7 under 35 U.S.C. §103(a) over *Gotsche et al* in view of *Castillo et al.* (US 5,091,185).

The *Castillo et al.* reference is cited only in an attempt to compensate for the *Gotsche et al.* reference's failure "to disclose that component B is a polyvinyl alcohol having a degree of hydrolysis of between 80 and 90 mol%."⁶ Thus, even before analyzing whether an apparent reason existed for a skilled artisan to combine these two references, one can conclude that claim 7 is unobvious over the cited combination. As discussed above, the *Gotsche et al.* reference is inadequate to establish a case of *prima facie* obviousness with regard to the invention of claim 1. The reference provides no apparent reason to select component A from an enormous genus, no apparent reason to select component B from a broad genus, and no apparent reason to combine component A and component B. In other words, claim 1 could not properly be rejected under 35 U.S.C. §103(a) over *Gotsche et al.* in view of *Castillo et al.* It is well-settled that "if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious."⁷ Thus, claim 7, which depends from claim 1, is nonobvious.

For the sake of completeness, Applicants reemphasize that the film coatings according to the present invention are meant to dissolve quickly. A skilled artisan, aiming at a quick dissolving film coating would not have added the component utilized by *Castillo et al.* to the film coating of *Gotsche et al.*, because the *Castillo et al.* component is utilized to reduce the rate of release of a film coating on a pharmaceutical presentation. In response, the Office action states that Col. 5, lines 29 – 38 of the *Castillo et al.* reference clearly "teaches that polymers less than 100% hydrolyzed will result in

⁶ Page 3, lines 16 – 17 of the Office action of December 10, 2007.

⁷ MPEP §2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

a[n] increase in the rate of release.”⁸ This statement is inaccurate. The cited portion of the reference states:

The water sensitivity of PVA, or the rate at which it goes into solution, is controlled primarily by the degree of hydrolysis. Fully hydrolyzed polymers have a high degree of water resistance, and dissolve very slowly at temperatures below about 60°C. For purposes of the present invention, a low level of water sensitivity is desired and fully hydrolyzed polymers are preferred. Water sensitivity of PVA is also influenced to a lesser degree by molecular weight, with higher molecular weight polymers having increased water resistance.⁹

Finally, the Office action seems to have overlooked the synergistic effects disclosed in the present specification, which could not have been foreseen by the skilled artisan on the basis of the *Gotsche et al.* reference. As is explained on page 7, line 23 to page 9, line 35 of the specification, the combination leads to enhanced mechanical properties like elongation at break which are higher than the properties of the individual compounds or their respective proportionate values. Since the coatings contain 40% by weight of polyvinyl alcohol, a polymer which tends to become brittle and is not at all stable when stored on its own, the results shown on the 2nd table of page 8, reporting elongation at break after various storage times are especially surprising. The coatings remain stable even after 12 months.

Regarding Rejection III:

The Examiner should withdraw the rejection of claim 11 under 35 U.S.C. §103(a) over *Gotsche et al* in view of *Babaian et al.* (US 4,842,854). Claim 11 depends from claim 1. The Office action does not cite the *Babaian et al.* reference to compensate for the fact that a skilled artisan had no apparent reason to make the proposed selections and combinations from the *Gotsche et al.* reference. Instead, the Office action cites *Babaian et al.* in an attempt to compensate for the fact that “Gotsche fails to disclose that

⁸ Page 7, lines 9 – 10 of the final Office action mailed December 10, 2007

⁹ Col. 5, lines 29 – 38 of US 5,091,185.

component B comprises vinylpyrrolidone-(meth)acrylate copolymers.”¹⁰ Thus, claim 1 could not properly be rejected under 35 U.S.C. §103(a) over *Gotsche et al.* in view of *Babaian et al.* It is well-settled that “if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.”¹¹ Thus, claim 11 is unobvious, and the present rejection should be withdrawn.

Regarding Rejection IV:

The Examiner should withdraw the rejection of Claims 29 and 30 under 35 U.S.C. §103(a) over *Gotsche et al.* Claims 29 and 30 require components A and B and also require a minimum of 5% by weight of component C. More importantly, both of these claims depend from claim 1, and it is well-settled that “if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.”¹² As discussed above, claim 1 is unobvious over *Gotsche et al.* Thus, claims 29 and 30 are unobvious, and the rejection should be withdrawn.

In Conclusion:

The present application is in condition for allowance. Applicants request favorable action in this matter. In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner is welcome to contact the undersigned by phone to further the discussion.

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¹⁰ Page 4, lines 17 – 18 of the present Office action.

¹¹ MPEP §2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

¹² MPEP §2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).